

REMARKS

Claims 1, 6, 7, 46-51, 55, 57, and 59-63 are currently under examination in the Application. Applicants note that the Examiner has withdrawn claims 61 and 62 as allegedly directed to an invention that is independent or distinct from the invention originally claimed. By the above amendment, new claim 63 has been added and the specification has been amended to add a statement regarding federally sponsored research. It is urged that support for the above amendments can be found throughout the specification as originally filed and that none of the amendments constitutes new matter. In particular, support for full length WT1 can be found throughout the specification, for example, at page 8, lines 9-10; Figure 1; and SEQ ID NO:319. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Applicants wish to thank the Examiner for withdrawal of the previous rejections and for allowance of claims 1, 6, 7, and 47-51. Applicants also wish to thank the Examiner for acknowledgement of the Information Disclosure Statements filed July 11, 2003 and March 26, 2004.

Withdrawn and Newly Added Claims

The Action has withdrawn claims 61 and 62 as allegedly directed to an invention that is independent or distinct from the invention originally claimed. The Action contends that the previously examined species (now claim 57) encompasses peptides comprising SEQ ID NO:144 that are less than amino acids 1-249.

Applicants respectfully traverse the Action's grounds for withdrawing these claims and submit that the claims previously examined include, among others, claims directed to a polypeptide that comprises the polypeptide set forth in SEQ ID NO:144 (for example,

Applicants refer the Office to the claims recited in Applicants' Response to Restriction Requirement and Preliminary Amendment filed July 25, 2002). Thus, Applicants submit that the subject matter of claims 61 and 62, and newly added claim 63, may be properly examined along with the other pending claims. Applicants respectfully request reconsideration and request that these claims be examined with the other pending claims.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 57, 59, and 60 stand rejected as allegedly being obvious under 35 U.S.C. § 103 over Herlyn *et al.* (WO 95/29995) in view of Jager *et al.* (US Patent No. 6,096,313). Specifically, the Action alleges that Herlyn *et al.* teach a peptide comprising SEQ ID NO:144 in that SEQ ID NO:144 is found in amino acids 1-181 of human WT1 described by the authors. The Action further contends that Herlyn *et al.* teach that the polypeptide is immunogenic (*e.g.*, induces antibodies) and that it consists of no more than amino acids 1-249 of WT1. The Action concedes that Herlyn *et al.*, do not teach the use of GM-CSF but asserts that this deficiency is overcome by combination with the teachings of Jager *et al.*

Applicants respectfully traverse the rejection. Applicants maintain that the cited references, taken either alone or in combination, cannot reasonably render obvious the presently claimed invention. In particular, Applicants reiterate that Herlyn *et al.* teach the use of a fragment of WT1 consisting of amino acids 1-181 merely as a tool to generate antibodies in mice. Nowhere does Herlyn *et al.* teach or even suggest that a WT1 polypeptide consisting of no more than amino acids 1-249 of WT1 wherein said polypeptide comprises the amino acid sequence of SEQ ID NO:144, or any portion of WT1 for that matter (*e.g.* a portion that comprises SEQ ID NO:144 but that does not comprise full-length WT1), would be capable of effectively eliciting a T cell response. Further, Herlyn *et al.* do not even suggest that it would be desirable to elicit a WT1-specific T cell response. Jager *et al.* simply describe the use of GM-CSF as an adjuvant. Nowhere does this reference teach or suggest WT1 or any peptides or immunogenic fragments thereof.

Even assuming *arguendo* that the cited references show elements of Applicants' invention, there is no motivation for a skilled artisan to combine the cited references in order to

arrive at Applicants' claimed invention. As discussed in Applicants' reply filed in response to the Office Action dated February 21, 2003, in order to properly support a *prima facie* case of obviousness, the Examiner must show a motivation to combine the references. To this end, the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998). Contrary to the Action's assertions, Applicants submit that the skilled artisan would have had no motivation to combine the cited references to arrive at Applicants' invention. In particular, the Action alleges that using GM-CSF as taught by Jager *et al.* and the polypeptide taught by Herlyn *et al.*, the routineer would have achieved superior results when immunizing animals to produce antibodies. Applicants submit that the skilled artisan would readily appreciate that producing antibodies by immunizing a mouse and eliciting a T cell response are not the same. Given the teachings of Herlyn *et al.*, the skilled artisan would have had no motivation to combine the polypeptides taught therein with GM-CSF because there is simply no teaching by Herlyn *et al.* that WT1 is capable of eliciting a T cell response.

Without motivation to combine the prior art references, a skilled artisan would select and combine elements from the prior art only by examining the problem in hindsight. The Federal Circuit has firmly rejected such hindsight reconstruction used to "pick and choose among isolated disclosures in the prior art" to arrive at Applicants' invention. *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). To this end, Applicants submit that no specific reasoning has been given for a skilled artisan to combine the cited prior art references. Accordingly, Applicants submit that the cited prior art references support only a mere hindsight reconstruction of Applicants' invention.

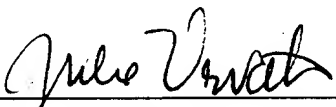
In light of the above remarks, Applicants respectfully submit that the claimed invention is not obvious in view of the cited references and respectfully request reconsideration and withdrawal of the rejection.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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